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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

BNSF,

Plaintiff,

vs.

CARD,

Defendant.

CV-19-40-M-DLC

CARD's BRIEF IN SUPPORT OF MOTION FOR JUDGMENT AS A MATTER OF LAW RE: STATUTE OF LIMITATIONS AND ELEMENTS OF FALSE CLAIM, SCIENTER, AND MATERIALITY

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I. INTRODUCTION

Defendant Center for Asbestos Related Disease ("CARD") makes this motion for judgment as a matter of law, pursuant to Fed. R. Civ. P. Rule 50(a) on four distinct bases. First, Relator filed its complaint in March 2019 outside the applicable statute of limitations, because either (1) U.S. officials knew or reasonably should have known of material facts no later than January 2016 or (2) U.S. officials did not learn of the material facts until this lawsuit, meaning the six-year limitations period applies. Second, the plain language of the ACA provisions expressly authorizes Medicare benefits for those with positive B-reads such that no false statements were made. Third, the uncontradicted facts establish that CARD's practice of submitting positive B-reads to SSA was consistent with its understanding of the purpose of the ACA provisions and amounts to a "good faith interpretation" which forecloses the possibility that Relator can prove scienter. Finally, even if CARD's submissions were false, they were not material as the uncontradicted facts show that the government, with full knowledge of the practice continued to approve the submissions for Medicare benefits, support CARD with grant approval, and declined to proceed with claims against CARD.

As described below, the facts presented and controlling law entitles CARD to a judgment that (a) Relator filed its complaint outside of the applicable statute of limitations, (b) CARD did not make false statements, (c) CARD did not have the

requisite scienter, and (d) any submissions based on CARD's good faith interpretation were not material as evidenced by responses by the Agency for Toxic Substances and Disease Registry ("ATSDR"), Social Security Administration ("SSA") and the Department of Health and Human Services Office of Inspector General ("HHS OIG").

II. LEGAL STANDARDS

A. Entitlement to Judgment as a Matter of Law

If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient basis to find for the party on that issue, the court may grant a motion for judgment as a matter of law against that party on that issue. FRCP 50(a)(1). In reviewing a motion for judgment as a matter of law, the court should review "all of the evidence in the record" and "draw all reasonable inferences in favor of the nonmoving party." *Reeves v. Sanderson Plumbing Prods.*, 530 U.S. 133, 150 (2000). The court should not make "credibility determinations or weigh the evidence," but instead "give credence to the evidence favoring the nonmovant *as well as* that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.'" *Id.* at 150-51 (quoting 9A C. Wright & A. Miller, Federal Practice and Procedure § 2529, pp. 299-300 (2d ed. 1995)).

B. Applicable Statute of Limitations

31 U.S.C. § 3731(b) prescribes the time period in which a civil action under § 3730 may be brought: within either (1) six years after "the date on which the violation" occurred, or (2) three years "after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances." The second triggering event, when an "official of the United States" learns the material facts, essentially tolls the six-year period in section (b)(1). This extends the limitations period by three years, but "in no event more than ten years," from the date of the violation. § 3731(b)(2). In applying this statute, whichever period provides the later date serves as the limitations period. *Id.*; *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1510 (2019). For example, for a violation occurring in 2010, the earliest applicable limitation date would be 2016, and the latest 2020, *if and only if*, the US official learned the material facts no earlier than 2017.

C. False Claims Act Elements

Claims under the False Claims Act ("FCA") require a showing of "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902 (9th Cir.

2017); *accord United States. ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 179 (4th Cir. 2022). Under 31 U.S.C. § 3731, the United States, or Relator on behalf of the United States, must prove all essential elements of the cause of action by a preponderance of the evidence. *See United States ex rel. Heath v. Wisconsin Bell, Inc.*, 593 F.Supp.3d 855, 859 (E.D. Wis. 2022).

1. False Statement

Relator must show that CARD made false statements either expressly or impliedly via omissions of "its violations of statutory, regulatory, or contractual requirements . . . if [those omissions] render the defendant's representations misleading with respect to the goods or services provided." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016). "The FCA requires the knowing presentation of what is known to be false and that the phrase known to be false does not mean 'scientifically untrue,' it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors." *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*, 953 F.3d 1108, 1117-18 (9th Cir. 2020) (citations omitted).

2. Scienter

The scienter requirements of the FCA are "rigorous." *Escobar*, 579 U.S. at 192. To prove the element of scienter, there must be proof that rises above the level of "innocent mistake" or "mere negligence." *United States ex rel. Hagood v. Sonoma*

Cty. Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991). Further, a defendant who relies on "a good faith interpretation of a regulation is not subject to liability" under the FCA. *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir. 1999). This is true even if that interpretation was incorrect or unreasonable, "because the good faith nature of his or her action *forecloses the possibility* that the scienter requirement is met." *Id.* (emphasis added).

3. Materiality

Under the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. §3729(b)(4). The FCA "is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar,* 579 U.S at 194 (internal citations omitted). The false claim or statement must be the "*sine qua non* of receipt of state funding" *Gilead Scis., Inc.*, 862 F.3d at 902 (citation omitted). Moreover, materiality "cannot be found where noncompliance is minor or insubstantial." *Id.*

III. RELEVANT FACTS

A. Alleged violations occurred beginning in 2010; alternatively, U.S. officials learned of material facts no later than January 2016.

Beginning in 2010, after the enactment of the Patient Protection and Affordable Care Act ("ACA"), CARD began submitting claims for Libby residents affected by asbestos exposure to SSA.

In 2015, in response to complaints that CARD providers were "over diagnosing" asbestos related diseases, HHS OIG launched an investigation of CARD. Dkt#74-40. As part of that investigation CARD provided HHS OIG with CARD's grant application, quarterly reports on work being done under the grant, and Dr. Black's publication in the American Journal of Industrial Medicine regarding lamellar pleural thickening. Dkt#74-37, 74-38. HHS OIG discussed the complaint and findings with the prosecutor's office. Dkt# 74-40. HHS OIG also requested from Medicare and received on January 22, 2016 "data for all Medicare claims, part B, submitted by Dr. Charles Black and Dr. Alan Whitehouse from January 1, 2010 to the present." Dkt# 74-39. Following its review of all the facts material to the bases of the present inquiry into CARD's submissions for Medicare eligibility under the Act, HHS OIG concluded its investigation and did not bring any claims against CARD. CARD's interpretation of the Act and its policies regarding

submission of Medicare eligibility applications under the Act were apparent to the HHS OIG by no later than January 22, 2016.

B. Plain language of relevant provisions of the Affordable Care Act.

In 2010, the ACA was passed into law. 42 U.S.C. §18001. Section 1881A allowed for Medicare coverage for individuals exposed to environmental health hazards. 42 U.S.C. §1395rr-1. Under the ACA, an individual who meets certain qualifications qualifies for Medicare coverage. These qualifications include an individual diagnosed with "asbestosis, pleural thickening, or pleural plaques as established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or (II) such other diagnostic standards as the Secretary specifies." §1881A(e)(2)(B). Dkt# 74-5. Although there is significant discretion offered to the Secretary of Health and Human Services, the plain language of the law is clear that eligibility for Medicare under the ACA can be obtained based on positive findings of asbestos related disease noted by "interpretation by a B-Reader." ACA provisions provide that regardless of whether the diagnosis of an ARD is made by CARD or whether the determination is made by an outside reader, either results in eligibility for Medicare benefits. Dkt# 74-5; §

1881A(e)(2)(B)(i)(I). "Qualified physician" is not defined by these Libby provisions.[1]

C. CARD's involvement in development of ACA provisions and subsequent implementation.

In 2009 to 2010, congressional and ATSDR officials came to Libby to meet with CARD to discuss provisions to include in the anticipated ACA. That government delegation met with key personnel at CARD, including Dr. Brad Black and Tanis Hernandez.

The congressional delegation sought CARD's input regarding requirements to include in the ACA for individuals to qualify for Libby Medicare. Based on CARD's prior experience with other benefit programs for victims of Libby asbestos, such as FLASH, the group collectively determined that it was important to remove the requirement of a confirmation of a CARD diagnosis with an outside read (either B reader from a chest x-ray or positive CT read). For example, FLASH required two positive x-ray B reader or CT findings. Because Libby disease can be difficult to detect on an x-ray and there is recognized variability between radiologic interpretations (whether on x-ray or CT scan), the government delegation and CARD

[1] *See* 42 U.S.C. § 1395x, Definitions. "The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action . . . ."

jointly recognized those requirements could cause many persons affected by Libby asbestos disease to be ineligible for the intended Libby Medicare. Thus, the government delegation drafted the language of the ACA eligibility provisions to require: one positive x-ray interpretation by a B reader or the interpretation of CT by qualified physician (as determined by the Secretary). The understanding by the government delegation and CARD was that the Secretary was going to specifically identify CARD physicians as "qualified physicians."

Thereafter, the ATSDR language in its funding requests mirrors language of ACA but goes further in that regard and specifically states that CARD doctors are qualified physicians and, thus, that a diagnosis based on their interpretation of a CT read is sufficient for eligibility. As such, CARD reasonably believed and understood based on its discussions with the government delegation and key personnel at ATSDR that after the passage of the ACA, CARD staff were to advise individuals they qualified for Libby Medicare if they had either: one outside x-ray found by a by B reader to be indicative of asbestos-related disease or the interpretation of CT by a CARD physician or another qualified physician. This interpretation of the Act's eligibility provisions is consistent with the testimony of CARD staff and physicians at trial regarding their understanding of the provisions, the testimony regarding the intent and purpose of the provisions as offered by its drafter and primary proponent Senator Baucus, and the plain language of those provisions:

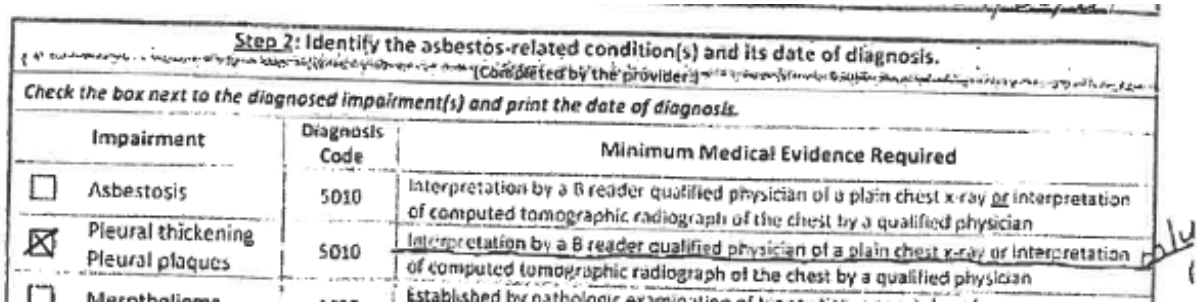
> "…. asbestosis, pleural thickening, or pleural plaques as **established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray** or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or (II) such other diagnostic standards as the Secretary specifies."

42 USC §§18001, 1881A(e)(2)(B) (emphasis added).

The FLASH program overlapped with the initial implementation of the ACA for a few years. CARD staff, under direction of Tanis Hernandez, implemented the FLASH form for submission of individuals under the ACA. That form included text regarding verification that the individual had been diagnosed with an asbestos related disease and then one of two boxes had to be checked: one box said diagnosis by a B reader, one box said interpretation of CT. At no time during the course of using those FLASH forms did the SSA indicate to CARD there was any issue with the form itself or inform CARD that diagnosis based on B-read alone was insufficient for eligibility.

While these forms submitted to the SSA clearly state some individuals were diagnosed via B-read only, with often CARD staff doing more than just checking the box and additionally writing "B read only" to alert SSA to this means of eligibility, CARD did not separately communicate to SSA that some people were being diagnosed via B-read only. At no time during the submission of those forms did SSA contact CARD about those forms or that it would be improper to submit the form based on a B-read only. During this litigation, SSA has recently taken the

position that it did not know CARD was submitting forms for individuals seeking eligibility based on B-read only despite clear documentary evidence to the contrary:



Step 2: Identify the asbestos-related condition(s) and its date of diagnosis.
(Completed by the provider)

Check the box next to the diagnosed impairment(s) and print the date of diagnosis.

	Impairment	Diagnosis Code	Minimum Medical Evidence Required
☐	Asbestosis	5010	Interpretation by a B reader qualified physician of a plain chest x-ray or interpretation of computed tomographic radiograph of the chest by a qualified physician
☒	Pleural thickening Pleural plaques	5010	Interpretation by a B reader qualified physician of a plain chest x-ray or interpretation of computed tomographic radiograph of the chest by a qualified physician
☐	Mesothelioma		Established by pathologic examination of tissue

See Dkt# 74-49 at 2.

D. ATSDR and SSA's knowledge and response.

In 2011, ATSDR awarded CARD a four-year grant to conduct screening activities under the ACA. ATSDR awarded two subsequent grants to CARD, essentially extensions of 2011 grant, for the periods 2015-2019 and 2019-2024. As part of compliance with the terms of the grants, CARD has submitted annual reports and budget justifications to ATSDR; submitted quarterly reports to ATSDR; and CARD staff has worked closely with ATSDR to ensure compliance with the terms of the grants. Included in the grant reports is information about how CARD implements the EHH checklists. *See* Dkt#74-34, 187:23-188:2; Dkt#74-18 at 9. Almost all of CARD's funding comes from the ATSDR screening grants. At no time has ATSDR rejected or questioned CARD's implementation of the ACA.

As part of the ATSDR grants, CARD established a panel of B-Readers to review plain chest x-rays and CT scans of screening participants, and CARD staff

sent radiographic images of patients to the outside readers for interpretation. The outside readers fill out a form for each chest x-ray or CT scan they interpret and send the forms back to CARD. If an outside reader interprets an asbestos-related condition or a qualifying condition on a radiographic image, and the patient requests it, CARD staff fill out an EHH checklist and designates that the asbestos-related condition or qualifying condition was determined by an outside reader. This is a designation not required on the EHH checklist, but used for recordkeeping and grant reporting by CARD. The EHH checklist is then signed by a CARD physician. CARD forwards the EHH checklist to the Social Security Administration. At no time has SSA rejected or questioned CARD's implementation of the ACA provisions.

IV. ARGUMENT

A. Relator's Complaint was filed after the applicable statute of limitations passed.

Following the U.S. Supreme Court's interpretation of §3731(b) in *Cochise*, the 9th Circuit has not reported a case applying its holding. In the memorandum opinion in *Houpt v. Wells Fargo Bank, N.A.*, 800 Fed.Appx. 533 (9th Cir. 2020) (unpublished), the Court found the Relator's claims were barred under both provisions of §3731(b). First, the six-year limitation attaches to the "claim for payment." *Id.*, 800 Fed.Appx. at 534. Further, in applying the three-year limitation, the Court attached the limitation to the date the agency to which the claim was submitted, namely the U.S. Small Business Administration (notably, *not* the

Department of Justice or Office of Inspector General), "knew or should have known" the material facts. Although not precedential, this case is a common-sense application of the interpretation in *Cochise* that the extension of the statute of limitations from the date the U.S. official learned of the material effects underlying the claim is only three years, not ten.

Applying *Cochise*'s holding to various hypotheticals clarifies this rules application. For example, if an alleged violation occurred in March 2010, Relator would have until March 2016 to file its complaint under §3731(b)(1). However, this deadline can change depending on when a U.S. official knew or should have known material facts under §3731(b)(2). For example, if the HHS OIG learned of all material facts underlying a claim in 2011, then the rule would provide that Relator must file by 2014 under the three-year limit, or 2016 under the six-year limit. Since the later date applies, Relator would have until 2016 to file. If the HHS OIG did not learn of the material facts underlying a claim until 2017, *after* the six-year limitation had passed, Relator gets an additional three years to file the complaint—by 2020. However, if the HHS OIG did not learn of the material facts underlying a violation beginning in 2010 until 2018, Relator would still have to file by 2020, because of the 10-year cap.

In this case, the earliest alleged violation occurred in 2010, at which time the facts material to the presently alleged violations accrued. Under §3731(b)(1), the

Relator would have had until 2016 to file this qui tam action or would be time-barred. If, and only if, a U.S. official later obtained sufficient knowledge of the material facts underlying alleged violations, Relator would get an additional three years to file the claim, but in no event, later than 2020. In this case, by December 2015, or at the very latest January 22, 2016, HHS OIG was on notice of the materials facts underlying the alleged violations of the ACA. *See, e.g.*, 2015 Report to ATSDR expressly describing CARD's implementation of B-read only Medicare submissions, disclosed to HHS OIG, Dkt# 74-44 at 20. Those dates would trigger the §3731(b)(2) limitations period of three years—therefore, Relator was time-barred, at the *very latest* to bring this action by January 21, 2019. This action was filed in March 2019, at least two months too late even under the most generous interpretation of the facts.

Moreover, if the Court adopts Relator's contention that the relevant U.S. officials did *not* have notice by December 2015 or January 2016, then the triggering event of §3731(b)(2) did not occur until after the commencement of this lawsuit, and therefore, the six-year statute of limitations applies. As a result, claims regarding CARD's submissions occurring prior to March 2013 are time-barred under § 3731(b)(1).

B. CARD is entitled to a judgment as a matter of law because it did not make false statements to SSA.

1. The plain language of the ACA defines "diagnosis" to include B-read interpretations, not ATS criteria.

To be eligible for Medicare benefits under 42 U.S.C. §1395rr-1, the person must have either "asbestosis, pleural thickening, or pleural plaques as established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or (II) such other diagnostic standards as the Secretary specifies."

In statutory interpretation, the analysis begins with the express language of the statute. *Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 450 (2002). The first step "is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." *Id.* (citing *Robinson v. Shell Oil Co., Inc.*, 519 U.S. 337, 340 (1997) (internal citation omitted)). The inquiry is complete if "the statutory language is unambiguous and 'the statutory scheme is coherent and consistent." *Id.* When interpreting the statute's language, the court "generally seeks to discern and apply the ordinary meaning of its terms at the time of their adoption. *BP P.L.C. v. Mayor and City Council of Baltimore*, 141 S. Ct. 1532, 1537 (citing *Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1479–1480 (2021).

This Court's analysis should begin and end with the plain language of the statute. Although Relator has attempted to cast doubt on what the statute provides by conflating the requirements for eligibility under the Act with its interpretation of what may be necessary for a treating physician to arrive at a clinical diagnosis of asbestos related disease—the statute itself makes plain that, for purposes of eligibility under the Act, a "diagnosis" of asbestosis, pleural thickening or pleural plaques can be established by either positive B-read by a qualified physician or a CT interpretation of a qualified physician. Notably absent from the statute is a requirement that the "diagnosis" conform to any outside standards, such as the 2004 American Thoracic Society Guidelines. Instead, the language is drafted broadly, and therefore, must be construed as broadly as it is written.[2] Further, testimony from the designated FRCP 30(b)(6) deponent of the ATSDR, Theodore Larson, clarified that ATS Guidelines are not specified in the ACA or ATSDR's Notice of Funding Opportunities, and funding for CARD under the ACA is not predicated upon CARD following ATS Guidelines. Theodore Larson Testimony 82:23-24; 85:13-15.

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[2] Even so, CARD physicians' clinical diagnoses for asbestos-related diseases *are* based on the 2004 ATS Guidelines. Dkt# 74-35 at 17:14-18:23. CARD providers' clinical diagnoses of patients with asbestos-related diseases are based on over two decades of familiarity with the presentation of Libby amphibole disease in patients.

2. Even if ambiguous, the legislative history makes clear the provision was meant to be inclusive, with broad application of "diagnosis" and to include CARD physicians as "qualified physicians."

Relator attempts to interject ambiguity into the statute regarding the meaning of "diagnosis," despite the fact that the salient inquiry here is Medicare eligibility, which can be established, per the plain language of the Act, via a positive B-Read. Where a party asserts the language of a law is ambiguous, the courts may properly use the legislative history to reach a conclusion as to the meaning of the law. *United States v. Pub. Utilities Comm'n of Cal.,* 345 U.S. 295, 315 (1953). Statutes do not exist in a vacuum and considering this language in the broader context, "the background of the legislative history . . . and the historical context from which the Act arose" "makes clear that an interpretation of the sections that" were intended to increase access to Medicare benefits to those affected by Libby asbestos exposure would "'bring about an end completely at variance with the purpose of the statute' and must be rejected." *United Steelworkers of Am., AFL-CIO-CLC v. Weber*, 443 U.S. 193, 201-02 (1979) (quoting *Pub. Utilities Comm'n of Cal*., 345 U.S. at 315).

Here, the Congressional Record provides that the relevant provisions would "finally follow through on the Federal Government's responsibility to provide screening and medical care to residents at Superfund public health emergency sites." Dkt# 188-3, at 6. When a public health emergency is declared "the law requires that the Secretary of Health and Human Services provide screening and medical care

services to people who have been exposed." *Id.* "Medical care in Libby has historically been limited due to Libby's isolated location and economic situation, thus reducing the chance of early detection and treatment of asbestos-related disease." *Id.* at 9. The provisions were intended to "provide vital medical services to Americans who, through no fault of their own, have suffered horrible effects from their exposure to deadly poisons" that Congress committed to through the Superfund Act. *Id.* at 6-7. The Congressional Record confirms the recognition in passing the provisions that Libby asbestos disease was often not recognized by doctors unfamiliar with the condition, necessitating the broad eligibility terms ultimately included therein:

> Let me refine that point. For a long time, we have been talking to lung specialists across the country about the Libby tremolite asbestos, and we got just so-so responses about how dangerous it was. Why? Because virtually none of those doctors had experience dealing with the pernicious kind of asbestos we have in Libby, MT. It took a long time to get their attention. We finally got some doctors to say this stuff in Libby is wicked stuff. That is why, frankly, EPA has started to understand how bad this really is.

Id. at 9. The legislative intent of the eligibility provisions as written is elucidated in detail in the excluded testimony of Senator Baucus, the primary proponent and drafter of the provisions at issue.

Considering the plain language of the provisions in conjunction with the legislative history makes clear that Relator's attempted interpretation would limit Libby residents' access to necessary medical care "bring[ing] about an end

completely at variance with the purpose of the statute" and should be rejected by this Court. *United Steelworkers of Am.*, 443 U.S. at 201-02. Moreover, if the statute were ambiguous as asserted, CARD's interpretation of the allegedly ambiguous provision was certainly reasonable based on the plain language therein and the record of legislative intent, and as discussed more fully below, would not meet Relator's burden to show CARD acted knowingly. *Gugenheim*, 36 F.4th at 161 (where possibility of proving scienter foreclosed when defendant relies on "sufficiently ambiguous" agency interpretation).

C. The evidence of CARD's subjective understanding of how the ACA provisions operate shows it acted without the requisite scienter.

In the recently decided *United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391 (2023), the Supreme Court discussed the required proof of the element of scienter: "The FCA's scienter element refers to respondents' knowledge and *subjective* beliefs—not to what an objectively reasonable person may have known or believed." *Id.*, 143 S. Ct. at 1399 (emphasis added). Relator is required to prove CARD's actions were performed knowingly by either having "actual knowledge," acting with "deliberate ignorance of the truth or falsity of the information," or acting "in reckless disregard of the truth or falsity of the information." § 3729(b)(1)(A)(ii)-(iii). This three-part test "largely tracks the traditional common-law scienter requirement for claims for fraud." *SuperValu*, 143 S. Ct. at 1399 (citing Restatement (Second) of Torts §526 (1976); Restatement (Third) of Torts: Liability for Economic

Harm § 10 (2018)). Deliberate ignorance requires proof that CARD "shut [its] eyes to the facts, or purposely abstained from inquiring into them." *Id.*

Additionally, the Supreme Court clarified that the FCA requires proof of "what the defendant thought when submitting the false claim—not what the defendant may have thought *after* submitting it." *Id.,* 143 S. Ct. at 1401 (emphasis in original) ("the term 'knowingly' thus modifies present-tense verbs like 'presents.'"). Therefore, the focus of Relator's burden of proof cannot be on "*post hoc* interpretations" and instead must focus on what CARD knew at the time it presented the claim. *Id.* (citing *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 105 (2016) ("[C]ulpability is generally measured against the knowledge of the actor at the time of the challenged conduct")). Similarly, the Court should not look to "legal interpretations that respondents did not believe or have reason to believe at the time they submitted their claims." *Id.* 143 S. Ct at 1403.

Under the FCA, Relator must prove by a preponderance of the evidence the scienter element, namely CARD's "knowledge and *subjective* beliefs—not to what an objectively reasonable person may have known or believed." *SuperValu*, 143 S. Ct. at 1399. Here, the undisputed evidence establishes CARD's mental state at the time it submitted the EHH Checklists to SSA. That undisputed evidence demonstrates CARD staff's prior understanding through meetings with congressional delegates and the ATSDR that the ACA would limit barriers for Libby

residents affected by asbestos exposure to obtain Medicare benefits in very specific ways and provide inclusive coverage for individuals affected by asbestos exposure in Libby.

Evidence that CARD's interpretation of the actual ACA language was correct is not required to defeat a claim under the FCA. *Gugenheim*, 36 F.4th at 161. Further, where "policy and related guidance" from the agency is "sufficiently ambiguous," the possibility of proving scienter is foreclosed. *Id.* As the Fourth Circuit noted, "we cannot infer scienter from an alleged regulatory violation itself, and we 'especially' will not do so 'where there is regulatory ambiguity as to whether' Defendants' conduct even violated the policy." *Id.* (quoting *United States ex rel. Complin v. N.C. Baptist Hosp.*, 818 Fed. App. 179, 184 (4th Cir. 2020)). It is difficult to establish scienter even under "the loosest standard of knowledge, i.e., acting in reckless disregard" where the falsity turns on "a disputed interpretive question." *Id.* (citations omitted).

Relator has not proven that CARD had a subjective belief that amounted to, at minimum, a "reckless disregard" of their submissions. The evidence submitted by Relator does not show that CARD knowingly submitted false claims, or even that it should have sought more guidance about the allegedly ambiguous regulation. *Id.* at 181.

What the evidence shows establishes that Relator cannot meet its burden of proof that CARD had a subjective belief that at the time it submitted the EHH Checklists to SSA that it was submitting a false claim. First, CARD physicians met numerous times with congressional delegates to identify obstacles to (a) identifying Libby asbestos disease and (b) getting Libby asbestos victims Medicare benefits. Thereafter, SSA created the EHH checklists and provided CARD with the checklists after the Affordable Care Act was enacted. Dkt# 74-32. Moreover, CARD staff continue to work closely with SSA with the EHH checklists, Dkt# 74-33 ¶19; *see, e.g.,* Dkt# 74-6 ("If a claimant has been diagnosed with one of the impairments on that list, they qualify. So to us, either they are diagnosed, or they aren't").

At the time all the relevant submissions were made, SSA showed no signs of disapproval of CARD's practice; moreover, since being alerted of the practice, the SSA Office of Inspector General investigation did not recognize as unwarranted CARD's practice of submitting EHH Checklists to SSA that were clearly demarked as being based solely on B-reads. Further, according to the undisputed testimony of Stephanie Shaw, SSA has instructed CARD to continue to submit "B-Read only" EHH Checklists to SSA. Therefore, Relator is unable to provide sufficient evidence that CARD's practice of sending EHH Checklists to the SSA based solely on positive B-reads or on the basis of CARD physician radiographic interpretation was either a false statement/fraudulent course of conduct or material for purposes of the

False Claims Act. It certainly cannot prove that CARD had a "subjective belief" that its submissions were false or amounted to fraudulent conduct at the time the EEH Checklists were submitted. At a minimum, CARD's "good faith interpretation" of the relevant ACA provisions, in conjunction with "regulatory ambiguity" forecloses the possibility that Relator can establish the element of scienter by a preponderance of the evidence. *Gugenheim*, 36 F.4th at 161; *Complin*, 818 Fed. App. at 184.

D. The element of materiality is not met.

1. *Submissions of positive B-reads or of interpretations by CARD physicians were not material as evidenced by the conduct of SSA and ATSDR ratifying CARD's implementation of the ACA provisions.*

Relator has failed to show that these allegedly false submissions for Medicare benefits were material. "If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Escobar*, 579 U.S. at 195. "Under any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," meaning the government. *Id*. at 193 (citations omitted).

The provisions of the ACA were crafted to ensure that CARD physicians would be considered qualified to diagnose asbestos-related diseases. Dkt# 74-4. After passage of the ACA, the ATSDR sent out a Funding Opportunity Notice that specifically acknowledged that CARD physicians are considered qualified to diagnose asbestos related diseases. Dkt# 74-1 at 5. Throughout the years, ATSDR has issued three grants to CARD, and CARD has submitted quarterly reports, annual reports, and budget justifications to ATSDR. Dkt# 74-10 to 74-3; Dkt#74-18, 2016 Annual Progress Report to ATSDR, at 9-10, 18 ("An ARD screening result is considered positive if structural changes consistent with ARD are identified by a B reader on CXR or on CT if identified by either a CARD medical provider or a radiologist. … All individuals receiving positive screening results will be provided with one-on-one benefits education").

In its 2015 report to ATSDR, CARD could not have been more explicit in its description of how it implements the ACA provisions:

> During the grant there were 169 people who were not clinically diagnosed at CARD but who were eligible to receive Medicare benefits based on an abnormal outside B-read, CT read, or eligible asbestos related cancer. It has been a challenge to explain to screening participants how there are two different radiological read methods by which they could become eligible for Medicare benefits. … The dissention occurs because CARD's physicians diagnose screening participants with ARD based on American Thoracic Society guidelines versus radiology reads alone. … Any positive outside B-read or CT read also entitles the participant to Medicare benefits even if they have not been diagnosed clinically at CARD.

Dkt# 74-44 at 20, 2015 Final Report to ATSDR. ATSDR has been made aware of CARD's policies in regard to the Act and this distinction between positive screening and a clinical diagnosis since at least 2015. *See* 74-44 at 2 (distinguishing between ARD diagnosed and ARD Medicare eligible); 74-18 at 18-20. ATSDR is aware of CARD providers' diagnostic rates and rates of dissension with outside readers, yet ATSDR has continued funding the grants to CARD. 74-33, ¶¶ 13-15.

Further, the actions of SSA indicate that it is aware of how CARD staff fill out EHH checklists, since SSA created the EHH checklists and provided CARD with the checklists after the Affordable Care Act was enacted. Ex332. Moreover, CARD staff continue to work closely with SSA with the EHH checklists. Ex333 ¶19. As noted above, SSA presented CARD with an award for its "partnership" in providing Medicare benefits to individuals with asbestos-related diseases. Ex336. Further, testimony from SSA's Heather Hillman is that SSA has no role in how CARD or other physicians may fill out Step 2 or Step 3 of an EHH Checklist, and SSA relies on CARD and other physicians to follow §188A of the Act. Heather Hillmann testimony 51:3-9; 52:16-23.

What these unimpeachable and undisputed facts establish is that the effect of CARD's submissions to government agencies was to (a) continue to approve Medicare benefits based on positive B-reads and CARD physician diagnoses, and (b) continually approve and fund CARD's operations. CARD has never hid the ball

from SSA or ATSDR—rather, CARD staff has made clear their practices and implementation of the ACA provisions, from day one. Dkt# 74-33 ¶19; Dkt# 74-6; Dkt# 74-48 (clearing identifying the submission was based on positive B-read "only"). As such, all Agency action of record only demonstrates that any alleged violations were immaterial and that CARD policies in submitting Medicare eligibility applications were appropriate and reasonable.

2. *The record establishes that a portion of CARD's submissions would qualify for Medicare benefits based on age or other conditions regardless of their asbestos-related "diagnosis."*

Relator's claims in this case are overinclusive, irrelevant, and misleading for the simple reason that a portion of CARD's submissions to SSA would qualify for Medicare benefits even without a positive B-read or ATS diagnosis of ARD. For example, in CARD's 2016 Progress Report to ATSDR (Dkt# 74-18 at 9), CARD notes that by the end of the second quarter of year 01, of the 138 individuals who received the "EHH status" to be eligible for Medicare benefits, 98 individuals were over the age of 65. In CARD's 2015 Final Report to ATSDR, it noted, of the 2,509 EHH forms completed, 1,092 were for individuals over the age of 65. Dkt# 74-44 at 8, Table 11.

Further, in the December 5, 2019 "Report on Dr. Black and the Center for Asbestos Related Diseases" by the Office of Appellate Operations, Division of Quality, it is noted that anywhere from 31 to 46% of reviewed Medicare submissions

included individuals that would otherwise qualify for Medicare benefits "regardless of evidence from CARD/Dr. Black." Dkt#74-42 at 4-6. Therefore, as a matter of law, Relator cannot establish the final element under the FCA because the government would have issued those benefits regardless, and those claims should be excluded.

V. CONCLUSION

For the foregoing reasons, CARD respectfully requests this Court grant a judgment as a matter of law that (a) Relator filed its complaint untimely, (b) CARD did not make false statements, (b) CARD did not act with the requisite scienter and instead engaged in good faith application the plain language of the eligibility provisions of the Act as written, and (d) any statements made were not material.

DATED this 28th day of June, 2023.

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CERTIFICATE OF COMPLIANCE

I certify the foregoing brief has 6249 words and a Table of Contents and Table of Authorities are included in the brief.

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